Operating Under the New Compliance Environment: Considerations for the Pharmaceutical Industry

The Impact of the new Medicare Prescription Drug benefit

OIG HHS Was Ahead of the Curve

- Pharmaceutical industry came under scrutiny early on due to TAP settlement and pricing settlements.
- One of the motivating factors behind the model compliance guidance was the expectation of a prescription drug benefit.
- OIG HHS has great base of knowledge of compliance and rapidly increasing knowledge of the industry.

Overview

- Simple formula- Increase in spending = increase in scrutiny
- Government scrutiny of the pharmaceutical industry will continue to rise
  - Sales and marketing practices
  - CME programs
  - Sample distribution
- Government will be more involved with the pharmaceutical industry on a number of levels and different capacities
  - Establishing and auditing prices
  - Setting price controls
  - Negotiating drug prices for new drugs

Government Focus Areas—Overview

- Average Sales Price (2005) – Reporting a false price potential violation of the law.

- Increased CMS involvement in pricing – HHS will have authority to increase or decrease drug reimbursement based on market surveys.

Government Focus Areas (continued)

- Promotional relationships with physicians
- Sales and marketing activities
- Advisory Boards
- CME programs

Average Sales Price (ASP)

- ASP Based on actual market prices.
- New reimbursement formulas take effect January 1, 2005 and will be based rolling 12 month pricing
- Drug manufacturers to provide data quarterly to CMS, starting April 30, 2004
- Reimbursement for outpatient drugs administered in physician's office and other Medicare Part B covered drugs will be based on ASP for a minimum dosage unit

ASP (continued)

- ASP will have to include sales on which purchasers receive:
  - volume discounts
  - prompt pay discounts
  - cash discounts
  - free good contingent on any purchase requirement
  - chargebacks
  - rebates not otherwise excluded by the law

ASP (continued)

- Submit ASP calculations on quarterly basis
- False reports could be subject to prosecution under False Claims Act
- OIG will monitor market prices and will have the authority to challenge ASPs

ASP (continued)

- Old and New Fraud and Abuse Issues under ASP
  - ASP data now reported directly to government instead of publishers of pricing data as has been done for AWP
  - For brand drugs, reimbursement will be set at 106% of the lesser of ASP or WAC.
  - The further a drugmaker's lowest sale price is below ASP, the greater the fraud and abuse risk it faces

Implications

- Pricing decisions may be complex and risky
  - Customers will still seek discounts on drugs
  - This may lead sales forces to try to cultivate customers with the kind of non-price incentives (e.g., consultant relationships) that triggered fraud and abuse investigations in the AWP environment

Other Areas of Focus for OIG

- OIG will be looking more intently for fraud now that government will be paying more for drugs
  - Inappropriate influencing of prescribing by physicians and other health care professionals
- Areas of interest
  - All sales and marketing practices
    - Gifts to physicians
    - Consulting arrangements with physicians
    - Professional meetings
    - Speaker training programs
    - Grants
    - Off-label discussions

Other Areas of Focus for OIG

- Areas of interest continued
  - Continuing Medical Education (CME) programs
    - marketing disguised as education
    - payments to CME speakers, program content, and spending on attendees
    - Even if using third-party vendor for programs and meetings, does not absolve company of responsibility to ensure vendor operates in compliance with rules and regulations
    - Consider moving the development of education and funding of grants out of marketing
    - New ACCME standards for commercial support due out this year—will ensure separation of CME funders and providers

Other Areas of Focus for OIG (continued)

- Provision of samples
  - If physicians are dispensing samples of drugs covered by Medicare, federal government will be interested in whether it is reimbursing those doctors for free samples or if sampling is influencing prescribing decisions
  - Consider developing policy against providing samples for sale to avoid any question from the government
  - Be able to show that company monitors sales representatives for compliance with the policy
  - Consider omitting from sample packages the National Drug Code designation used in submitting reimbursement claims

Anticipating Issues For Part D

- Regulations not issued or final
- Traditional pricing enforcement shouldn't be an issue
- PDP involvement could introduce/increase underutilization/quality of care enforcement
- Product liability = false claim?
- Off label promotion
- The government will likely be keenly interested in "excessive cooperation" between manufacturers and PDPs.

The Auditor's Interest

- Not only is the government interested in your compliance, but your auditor is as well.
- Why?
  - Professional responsibilities arising from SAS 99
  - Materiality considerations under SAB 99
  - Management Integrity concerns
- What happens if the auditor becomes aware of a potential illegal act? A collision course between attorney-client privilege and the auditor's need to know.

Considerations

- Shore up sales and marketing policies to address:
  - samples
  - gifts
  - professional meetings and CME programs
  - consulting arrangements
  - payments to physicians and other health care professionals
  - promotion of off-label uses
- Monitor relationships with PDPs
- Consider the PhRMA Code and OIG Compliance Program Guidance in your compliance program

Considerations

- Train, re-train sales and marketing professionals. Keep good records.
- Take reasonable steps to ensure price and data reporting accuracy and subject it to audit procedures
- Document criteria for interraction with health care professionals
- Audit and Monitor!!!!!!!!!
- Design your compliance program to find gambling in Casablanca